K113406 FEB 13 2012

DENTSPLY

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## SECTION 5. 510(k) SUMMARY
## for
## Title of Submission

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: November 11, 2011

2. Device Name:

- Proprietary Name: AQUASIL ULTRA SMART WETTING IMPRESSION MATERIAL
- Classification Name: Material, Impression
- CFR Number: 872.3660
- Device Class: II
- Product Code: ELW

3. Predicate Device:

DENTSPLY International's:

- K021410- Aquasil Ultra XLV Smart Wetting Impression Material.
- K021413- Aquasil Ultra Rigid Smart Wetting Impression Material
- K021416- Aquasil Ultra Monophase, Heavy and LV Smart Wetting Impression Material.

4. Description of Device:

AQUASIL ULTRA SMART WETTING IMPRESSION MATERIAL is a two-part catalyst/base hydrophilic vinylpolysiloxane elastomeric impression material suitable for all dental impression techniques where a light body (wash) and/or medium/heavy body (tray) material would be desired by the operator. Aquasil Ultra Smart Wetting Impression Material is available in light-bodied, medium-bodied or heavy-bodied consistencies; and fast set, regular set or extended work time.

5. Indications for Use:

Aquasil Ultra Smart Wetting Impression Material is indicated for all dental impression techniques.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

There are no changes proposed in this premarket notification which affect the fundamental technological characteristics of the subject devices. The intent of this premarket notification is: 1). The addition of the contraindication, "Aquasil Ultra Impression Material is contraindicated for use with patients who have a history of severe allergic reaction to peppermint oil or any of the components"; 2). Clarification of warnings and precautions through the addition of warning against the use of the devices as a temporary reliner as well as a precaution regarding their use with polyether, polysulfide, or condensation silicone materials; 3). Consolidation of Indications for Use; and 4). Documentation of minor quantitative changes to the existing ingredients in the composition of the AQUASIL ULTRA XLV SMART WETTING IMPRESSION MATERIAL, AQUASIL ULTRA RIGID SMART WETTING IMPRESSION MATERIAL, and AQUASIL ULTRA MONOPHASE/HEAVY/LV SMART WETTING IMPRESSION MATERIAL cleared in premarket notifications K021410, K021413, and K021416, respectively. The changes described do not affect the substantial equivalence of the devices as originally cleared in premarket notifications K021410, K021413, and K021416.

Non-Clinical Performance Data.

*Toxicological Testing*

All of the components used in the subject impression materials have been used in the devices as cleared in premarket notifications K021410, K021413, and K021416. There are no changes to the material composition of the subject impression materials proposed in this premarket notification.

*Physical Properties*

The purpose of this premarket notification is the addition of a contraindication; clarification of warnings and precautions; and clarification of the Indications for Use of the existing AQUASIL ULTRA SMART WETTING MATERIALS previously cleared in premarket notifications K021410, K021413, and K021416. There are no changes affecting the fundamental technology and chemical composition of the subject materials. There are minor quantitative changes to the existing ingredients in the material composition, but these changes do not affect the physical characteristics and mechanical properties of the materials.

Clinical Performance Data.

Not applicable.

Conclusion as to Substantial Equivalence

AQUASIL ULTRA XLV, LV, MONOPHASE, HEAVY, RIGID, XTRA WASH and XTRA TRAY SMART WETTING IMPRESSION MATERIAL are substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

FEB 13 2012

Re: K113406
Trade/Device Names: Aquasil Ultra Smart Wetting Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: November 11, 2011
Received: November 18, 2011

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 113406

Device Name: AQUASIL ULTRA SMART WETTING IMPRESSION MATERIAL

Indications for Use:

AQUASIL ULTRA SMART WETTING IMPRESSION MATERIAL is indicated for all dental impression techniques.

| Prescription Use __X__ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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